Attachment 1

Summary of Safety and Effectiveness

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h)

General Information:

Product Name:	NSM-S15 MRI System
Product Model:	NSM-S15
CFR Section:	21 CFR Part 892.1000 Magnetic resonance diagnostic device
Classification Name:	System, Magnetic Resonance Imaging
Product Code:	LNH
Device Class:	Class II
Applicable Standard:	IEC60601-1, Medical electrical equipment - Part 1: General Requirements for Safety IEC60601-2-33, Medical electrical equipment – Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis 21 CFR Subchapter J, Radiological Health IEC60825-1, Safety of laser products-Part1:Equipment classification, requirement and user's guide DICOM 3.0 NEMA MS Series (MS1 – MS9)
Manufacturer:	PHILIPS AND NEUSOFT MEDICAL SYSTEMS CO., LTD. Neusoft Park, Hun Nan Industrial Area, Shenyang 110179, P.R.China
Distributor:	NEUSOFT MEDICAL SYSTEMS CO., LTD. No. 16, Shiji Road, Hunnan Industrial Area, Shenyang,Liaoning,China,110179
Submitter:	Contact : Tianyuehui Title : Manager of Quality Management Department Tel : 86-24-83660646 Fax : 86-24-83660563 E-Mail : Tianyh@neusoft.com Summary prepared : June 17, 2009

Safety and Effectiveness information

Intended Uses:

The NSM-S15 product is an imaging device, and is intended to provide the physician with physiological and clinical information obtained non-invasively and without the use of ionizing radiation. The MRI system produces transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by MRI system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

Device Description:

The NSM-S15 product is a 1.5T superconducting magnet MRI system. The operating software based on Windows XP. The system software is an interactive program with user-friendly interface. Its functions cover scanning control, image reconstruction and image/archive management and maintenance.

Predicated Device:

K071925: MAGNETOM ESSENZA
K071154: Superstar 0.35T

Statement of Substantial Equivalence:

The NSM-S15 product is a 1.5T superconducting magnet MRI system. It is comparable and substantially equivalent to the MAGNETOM ESSENZA (K071925) and Superstar 0.35T (K071154) in that they are similar in technology and intended uses. Both of these systems use Gradient Subsystem to provide controlled and uniform gradient magnet fields in the X, Y and Z planes, and use RF Subsystem to complete the function of RF signal transmitting/receiving and processing. Image reconstruction is controlled by console' s computer that has an interactive user interface, and the system produces 2D and 3D image that can be filmed or electronically stored for future review. Both of these systems have the traditional MRI unit.

a. Non-clinical test: The device has been evaluated for performance, biocompatibility and effectiveness as well as electrical, mechanical, chemical , biocompatibility safety and has been found to substantially equivalent to MAGNETOM ESSENZA and Superstar 0.35T.

b. Clinical test: No clinical test conducted.

c. Conclusion: The device was evaluated against MAGNETOM ESSENZA (K071925) and Superstar 0.35T(K071154) for all performance, safety & effectiveness requirements. According to the comparison based on the requirements of 21.CFR 807.87, we state that these devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 0 9 2009

Neusoft Medical Systems Co., Ltd.
% Mr. Tamas Borsai
TUV Rheinland of North America, Inc.
12 Commerce Road
NEWTON CT 06470

Re: K092237
Trade/Device Name: NSM-S15 MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: August 20, 2009
Received: August 25, 2009

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SEP 09 2009

Attachment 2

Indications for Use

510(k) Number: _____ Page 1 of 1

Device Name: NSM-S15 MRI System

The NSM-S15 product is an imaging device, and is intended to provide the physician with physiological and clinical information obtained non-invasively and without the use of ionizing radiation. The MRI system produces transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by MRI system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

The indications for use are as follows:

Anatomical Region:	Head, Shoulder, Breast, Wrist, Body, Spine, Knee, Extremities
Nucleus excited:	Proton
Diagnostic uses:	T1, T2, proton density weighted imaging
	Diffusion weighted imaging
	MR Angiography
	Imaging processing
Imaging capabilities:	Spin Echo (SE and 3D SE)
	Fast Field Echo (FFE and 3D FFE)
	Inversion Recovery (IRFFE, IRSE)
	T1-FFE, T2-FFE, N-FFE (2D and 3D)
IR prepared T1-FFE3D	
	Dual Echo (DE) and Dual Spin Echo (DSE)
	Dual Fast Field Echo (DFFE)
	Turbo Spin Echo (TSE, 2D and 3D)
Single-shot TSE	
Dual Contrast Turbo Spin Echo (DTSE)	
	Driven Equilibrium Turbo Spin Echo
	IR TSE T2
	Balance Fast Field Echo (B-FFE and 3D B-FFE)
Diffusion-Weighted Imaging with DWISE and Fast DWISE	
	Echo Planar Imaging (EPI)

Prescription Use: YES (Part 21 CFR 801 Subpart D)

Over-The-Counter Use: NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF DEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K092237